

## WHAT IS CLAIMED IS:

1. An industrial process for recovering highly pure fentanyl from an impure preparation which comprises subjecting said impure preparation to a reverse-phase high performance preparative liquid chromatography and recovering highly pure fentanyl.
2. The process of Claim 1 wherein the loading ratio is in the range of from about 50 to about 150.
3. The process of Claim 2 wherein the loading ratio is in the range of from about 70 to about 130.
4. The process of Claim 1 wherein the stationary phase is selected from the group consisting of alkylsilanes, arylsilanes, haloalkylsilanes, alkyl esters, aryl esters, alkyl amines, alkylcyano compounds, alkyldiols, alkyl ethers, aryl ethers, haloalkyl ethers, alkylcarboxylic acids, arylcarboxylic acids, alkylsulfonic acids, arylsulfonic acids, polystyrenedivinylbenzene, aminopolycaprolactem and glycidoxyethylmethoxysilane.
5. The process of Claim 1 wherein the stationary phase is a bonded-phase silica containing ligands selected from the group consisting of butyl-, octyl- and octadecyl-moieties.
6. The process of Claim 5 wherein the ligand is octyl-silane.
7. The process of Claim 1 wherein the chromatography column is eluted with a mobile phase comprising an aqueous acidic solution containing an organic solvent.
8. The process of Claim 7 wherein the acid employed to acidify the solution is selected from the group consisting of acetic, formic, tartaric, hydrobromic, nitric and hydrochloric acid.
9. The process of Claim 8 wherein the aqueous mobile phase pH is in the range of from about 2.5 to about 3.5.
10. The process of Claim 9 wherein the pH is in the range of from about 2.8 to about 3.2.
11. The process of Claim 7 wherein the organic solvent is an alcohol.
12. The process of Claim 8 wherein the alcohol is selected from the group consisting of methanol, propanol, isopropanol, butanol and t-butanol.
13. The process of Claim 7 wherein the solvent is acetonitrile.
14. The process of Claim 1 wherein the impure preparation is acidified so as to prepare a fentanyl salt.
15. The process of Claim 14 wherein the acid employed to acidify the aqueous solution of fentanyl is an inorganic acid.

16. The process of Claim 15 wherein the acid is selected from the group consisting of hydrochloric acid, hydrobromic acid, phosphoric acid, phosphorous acid, sulfuric acid and nitric acid.
17. The process of Claim 14 wherein the acid employed to acidify the aqueous solution of fentanyl is an organic acid.
18. The process of Claim 17 wherein the organic acid is selected from the group consisting of acetic acid, formic acid, oxalic acid, succinic acid, lactic acid and tartaric acid.
19. The process of Claim 14 wherein the pH of the aqueous solution of fentanyl is in the range of from about 2 to about 5.
20. The process of Claim 19 wherein the pH of the aqueous solution of fentanyl is in the range of about from about 2.5 to about 3.5.
21. The process of claim 16 wherein the acid is hydrochloric acid.
22. The process of Claim 13 wherein the acetonitrile is in the range of from about 2 to about 100 volume percent.
23. The process of Claim 13 where the acetonitrile is in the range of from about 5 to about 10 volume percent during the collection of the purified fentanyl.
24. The process for purifying an impure preparation of fentanyl containing phenethylpiperaniline which comprises the steps of
  - (a) packing a chromatographic column with a chromatographic packing material;
  - (b) passing through said column an aqueous, acidified solution of impure fentanyl at a loading ratio of from about 50 to about 150 and
  - (c) eluting said column with an aqueous solution of an organic solvent to produce an eluate containing fentanyl having less than about 0.010 percent phenethylpiperaniline.
25. The process of Claim 24 wherein the eluate is divided into four cuts wherein:
  - (i.) a first cut is discarded,
  - (ii.) a second cut that is combined with a fourth cut wherein the water and organic solvent are substantially reduced and then recycled through the column, and
  - (iii.) a third cut that contains less than about 0.010 percent phenethylpiperaniline.